Product Assessment Report

Wood Protector przeciwogniowy impregnat do drewna FIRESTOP

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Biocidal product assessment report related to national authorisation under Biocidal Product Regulation 528/2012

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Contents

1 General information about the product application

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1.1.1 Person authorised for communication on behalf of the applicant

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1.2 Information about the product application

Application received:	30 August 2011
Application reported complete:	17 April 2012
Type of application:	National authorisation
Further information:	No

1.3 Information about the biocidal product

1.3.1 General information

Trade name:	*Wood Protector przeciwogniowy impregnat do drewna FIRESTOP*
Manufacturer's development code number(s), if appropriate:	–
Product type:	8 (wood preservatives)
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Boric acid 3% Disodium tetraborate 1%
Formulation type:	Liquid
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):**	No

1.3.2 Information on the intended use

Overall use pattern (manner and area of use):	▪ <u>Use classes:</u> – UC 1 (wood or wood-based product under cover and fully protected from the weather, not exposed to wetting) – UC 2 (wood or wood-based product under cover and fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting) ▪ <u>Application method:</u> – Painting – Brushing
Target organisms:	▪ Wood destroying *Basidiomycetes*: - *Coniophora puteana,* - *Gloeophyllum trabeum,* - *Poria placenta* ▪ Wood boring beetle: - *Hylotrupes bajulus,* larvae
Category of users:	Non-professional Professional
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	▪ 200 g product/m^2 in 2 or more coats against wood destroying basidiomycetes (6 g boric acid/m^2 and 2 g disodium tetraborate/m^2); ▪ 500 g product/m^2 in 4 or more coats against wood boring beetles (15 g boric acid/m^2 and 5 g disodium tetraborate/m^2)
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/ feedingstuff (yes/no)	No
Proposed Label:	-
Use Restrictions:	Please refer to section 2.9

1.3.3 Information on active substances

Active substance chemical name:	Boric acid	Disodium tetraborate
CAS No:	10043-35-3	1330–43–4
EC No:	233-139-2	215–540–4
Purity (minimum, g/kg or g/l):	> 990 g/kg	> 990 g/kg
Inclusion directive:	2009/94/EC	2009/91/EC
Date of inclusion:	01.09.2011	01.09.2011
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes	Yes

Manufacturer of active substances used in the biocidal product

Company Name:	US Borax Inc	ETI MADEN ISLETMELERI
Address:	14486 Borax Road	Korkutreis Mah., Cihan Sok. No:2
City:	Boron, CA	Sıhhiye Çankaya, Ankara
Postal Code:	93516-2000	06430
Country:	USA	Turkey
Telephone:	+ 1 760 762 7000	-
Fax:	-	-
E-mail address:	-	-

1.3.4 Information on the substance(s) of concern

Substance chemical name	benzyl-C12-14-alkyldimethyl, chlorides
CAS No:	85409-22-9
EC No :	287-089-1
Purity (minimum, g/kg or g/l):	≥99%
Typical concentration (minimum and maximum, g/kg, or g/l):	0.13% wag
Relevant toxicological/ecotoxicological information:	H302, H314, H400 P273, P280, P305 + P351 + P338, P 310
Original ingredient (trade name):	*Barquat MS-100*

1.4 Documentation

1.4.1 Data submitted in relation to product application

Please see to Annex 2.

1.4.2 Access to documentation

Dekspol P.P.H. Iwona Oleszak has letter of access (dated on 18 August 2011) to data held by European Borates Association A.I.S.B.L. which was used to supports the Annex I listing of the active substances boric acid and disodium tetraborate according to Directive 98/8/EC .

2 Summary of the product assessment

2.1 Identity related issues

The biocidal product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* contains two active substances – boric acid (3%) (purity > 990 g/kg) and disodium tetraborate (1%) (purity > 990 g/kg).
The source of active substances used in the biocidal product is identical to the active substances that is listed in Annex I of 98/8/EC.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification of the biocidal product

Product classification: None

2.2.2 Labelling of the biocidal product

The current Classification of Boric acid under Dir 67/548/EEC is:

T- Toxic
R60, R61

The current Classification of Boric acid under EC 1272/2008 is:
Repr. 1B, H360FD

The current Classification of Disodium tetraborate under Dir 67/548/EEC is:

T- Toxic

R60, R61

The current Classification of Disodium tetraborate under EC 1272/2008 is:

Repr. 1B, H360FD

Classification and labelling of the product under Dir 67/548/EEC is:

R-phrases

None

S-phrases

Keep out of the reach of children.

Classification and labelling of the product under EC 1272/2008 is:

Hazard statements:

None

Precautionary statements:

Keep out of the reach of children.

2.2.3 Packaging of the biocidal product

The packaging details for the biocidal product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP*, are outlined below for non-professional and professional users.

Packing type	Pack sizes for non-professional use	Pack sizes for professional use
Canister made of HDPE	5 kg	5 kg
Canister made of HDPE	10 kg	10 kg
Canister made of HDPE	20 kg	20 kg
Pail made of HDPE	-	25 kg
Pail made of HDPE	-	50 kg
Barrel made of HDPE	-	100 kg
Barrel made of HDPE	-	200 kg
Container made of HDPE	-	up to 1200 kg

2.3 Physical-chemical properties and analytical methods

The product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* is a water base ready for use liquid with following concentration of active substances: 3% of boric acid and 1% of disodium tetraborate.

Wood Protector przeciwogniowy impregnat do drewna FIRESTOP is odourless and colourless liquid with no oxidizing nor explosive properties. It is also not fulfilling a criterion for highly flammable and is not self igniting. Relative density of the product is equal to 1.095. Water suspension of the product gives light-acetic pH (1%, pH = 6.73 to 6.92 – after storage stability test).

Taking into consideration results from the accelerated storage stability test and also stability of technical characteristics, the shelf life of the product is considered acceptable up to two years in ambient conditions. The stability at low temperatures was confirmed.

The colorimetric method according to method described in AOAC. vol. 10 number 31.049, 31.050 and 31.051 with rules of GLP and SANCO/3030/99. rev.4 guide is acceptable for determination of the active substance content in the product.

2.3.1 Physical-chemical properties

Physical-chemical properties of the active substances:

The letter of access from European Borates Association A.I.S.B.L in short "EBA", granted to Dekspol P.P.H. Iwona Oleszak, has been submitted for the active substance therefore no additional information for this point is needed.

Physical-chemical properties of the biocidal product:

	Method	Purity/ Specification	Results	Reference
Physical state and nature	Polish Pharmacopoeia VI Edition (2002) and according to EPA Product Properties Test Guideline OPPTS 830.6302	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP, partia nr (lot No.) DP.10.05.11.P 95.	liquid	EMC Nr 373800019, BF-25/11
Colour	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP, partia nr (lot No.) DP.10.05.11.P 95.	colourless	EMC 373800019 study code: BF-25/11

	Method	Purity/ Specification	Results	Reference
	Guideline OPPTS 830.6303			
Odour	Farmakopea Polska, wyd. VI (2002) and according to EPA Product Properties Test Guidelines OPPTS 830.6304	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP, partia nr (lot No.) DP.10.05.11.P 95.	odourless	EMC Nr 373800019, BF-25/11
Explosive properties	n.a.	n.a.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP does not possess explosive properties	n.a.
Oxidizing properties	n.a.	n.a.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP does not possess oxidizing properties	n.a.
Flash point	n.a.	n.a.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP is not highly flammable	n.a.
Autoflammability	n.a.	n.a.	The self-ignition of Wood Protector przeciwogniowy impregnat do drewna FIRESTOP did not occur	n.a.
Other indications of flammability	n.a.	n.a.	n.a.	n.a.
Acidity / Alkalinity	CIPAC MT 75	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP, partia nr (lot No.) DP.10.05.11.P 95.	pH of 1% water suspension is 6.73 before and 6.92 after accelerated storage stability test	EMC Nr 373800019, BF-25/11
Relative density / bulk density	CIPAC MT 3.2	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP, partia nr (lot No.) DP.10.05.11.P 95.	Relative density is 1.095	EMC Nr 373800019, BF-25/11
Storage stability – stability and shelf life	CIPAC MT 46 (2 weeks 54 °C)	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP, partia nr (lot No.) DP.10.05.11.P 95.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP is stable for two weeks in 54 °C	EMC Nr 373800019, BF-25/11

	Method	Purity/ Specification	Results	Reference
Storage stability – stability and shelf life	CIPAC MT 39.3 (7 days at 0°C)	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP, partia nr (lot No.) DP.10.05.11.P 95.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP is stable at low temperature.	EMC Nr 373800019, BF-25/11
Effects of temperature	n.a.	n.a.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP is stable for two weeks in 54 °C. It is also stable at low temperature.	n.a.
Reactivity towards container material	CIPAC MT 46	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT, partia nr (lot No.) DP.10.05.11.P 95.	the weight, colour and shape of container as well as physical-chemical properties of product did not change during storage stability test	EMC Nr 373800019, BF-25/11
Technical characteristics in dependence of the formulation type ***Pourability***	CIPAC MT 148	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP, partia nr (lot No.) DP.10.05.11.P 95.	R_{av} = 0.22% R'_{av} = 0.16%	EMC Nr 373800019, BF-25/11
Persistence of foaming	CIPAC MT 47	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP partia nr (lot No.) DP.10.05.11.P 95.	After 1 min. 2 ml of foam	EMC Nr 373800019, BF-25/11
Compability with other products	n.a.	n.a.	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP will not be used with other products (especially biocidal products)	n.a.
Surface tension	n.a.	n.a.	n.a.	n.a.
Viscosity	n.a.	n.a.	n.a.	n.a.
Particle size distribution	n.a.	n.a.	n.a.	n.a.

2.3.2 Analytical methods

	Principle of method
Technical active substance as manufactured:	-
Impurities in technical active substance:	-
Active substance in the formulation:	Specific analytical method with validation data was established for determination of content of the active substance in the product. The colorimetric method according to method described in AOAC. vol. 10 number 31.049, 31.050 and 31.051 with rules of GLP and SANCO/3030/99. rev.4 guide. In this method the total content of borates was determined by spectrophotometer in UV in water solutions containing colour complex - product of reaction of borates with curcumin in acidic solution.

2.4 Risk assessment for physical-chemical properties

Based on the physical-chemical data submitted for *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* it can be concluded that there are no additional, specific physical-chemical risks for the product. The product has no explosive nor oxidizing properties. The product is not highly flammable and there are not autoflammability indications. A part of physical-chemical properties characteristics of the product is done before and after accelerated storage stability test. Due to test results, creation of persistent foam is expected to occur.

Taking into consideration results from the accelerated storage stability test, the shelf life of the product is considered acceptable up to two years in ambient conditions. The stability at low temperatures was confirmed.

2.5 Effectiveness against target organisms

2.5.1 Function

Product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* is ready-to-use wood preservative to preserve against wood destroying basidiomycetes and wood boring beetles. Certain efficacy data have been generated for the product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP*.

2.5.2 Field of usage

The product contains 3 % boric acid and 1 % disodium tetraborate. The product is intended to be used on wood above-ground in use classes 1 and 2[1].

According to label claims the product is efficient against wood destroying basidiomycetes and wood boring beetles.

The product is applied by superficial treatment (brushing/painting) to give an application rate of:

- 200 g product/m^2 in 2 or more coats against wood destroying basidiomycetes (6 g boric acid/m^2 and 2 g disodium tetraborate/m^2);
- 500 g product/m^2 in 4 or more coats against wood destroying basidiomycetes and wood boring beetles (15 g boric acid/m^2 and 5 g disodium tetraborate/m^2)

2.5.3 Effect of target organisms

Wood Protector przeciwogniowy impregnat do drewna FIRESTOP is 20 % water solution of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT*. Working concentration of both products is the same. Therefore results of efficacy tests conducted on one of the products are directly applicable to both products. In the text all results refer to ready for use product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP*, independently which product was tested, unless otherwise stated.

2.5.3.1 Wood destroying basidiomycetes

Study 1

In study conducted according to test standard PN-ENV 839, efficacy of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* was tested against wood destroying basidiomycetes.

The blocs used in the test were artificially aged according to PN-EN 73.

Table 2.1 Percentage of mass loss of virulence specimens

Test fungus/wood species	Mass loss		Average loss [%]	Requested minimal value according to PN-ENV 839
	[g]	[%]		

[1] According to *EN 335-1:2006, Durability of wood and wood-based products. Definition of use classes. Part 1:General*

				[%]
Coniophora puteana BAM Ebw. 15 Scotch pine sapwood	3.67 3.30 2.57 2.86 3.50 3.74	42.77 39.90 29.61 34.05 40.89 47.10	39.1	20.0
Gloeophyllum trabeum BAM Ebw. 109 Scotch pine sapwood	1.85 2.22 2.42 2.73 2.91 2.07	22.26 27.07 28.57 31.89 33.45 25.37	28.1	20.0
Poria placenta FPRL 280 Scotch pine sapwood	1.92 2.21 1.72 2.80 1.80 2.11	21.69 27.18 21.55 31.67 21.95 25.86	25.0	20.0

Toxic threshold concentrations in superficial application were determined as follows:

- *Coniophora puteana* 200 g/m^2 of ready for use product assuming wood density 0.51 g/cm^3
- *Gloeophyllum trabeum* 200 g/m^2 of ready for use product assuming wood density 0.51 g/cm^3
- *Poria placenta* 200 g/m^2 of ready for use product assuming wood density 0.51 g/cm^3

Biological reference value against basidiomycetes after evaporation is 200 g/m^2.

Study 2

In a second study conducted according to a standard PN-EN 113:2000/A1:2005, efficacy of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* was tested against wood destroying basidiomycetes.

The blocs used in the test were artificially aged according to PN-EN 73:1993.

In this study serial dilutions of product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* was tested.

Table 2.2 Toxic values for *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP KONCENTRAT* (arithmetic means of 6 replicates).

Test fungus/wood species	**Concentration of preservative solution**	**Preservative absorption [kg/m^3]**	**Average of the adjusted mass loss of the highest**

	[% (w/w)]		**concentration without protective effectiveness [%]**
Coniophora puteana BAM Ebw. 15 Scotch pine sapwood	0.25 – 0.40	1.49 – 2.42	23.7
Gloeophyllum trabeum BAM Ebw. 109 Scotch pine sapwood	0.25 – 0.40	1.51 – 2.43	6.2
Poria placenta FPRL 280 Scotch pine sapwood	0.25 – 0.40	1.53 – 2.45	6.4

Table 2.3 Percentage of mass loss of virulence specimens

Test fungus/wood species	**Mass loss [%]**	**Average loss [%]**	**Requested minimal value according to PN-EN 113:2000 [%]**
Coniophora puteana BAM Ebw. 15 Scotch pine sapwood	34.58 44.89 37.16 43.56 33.49 39.09	38.8	20.0
Gloeophyllum trabeum BAM Ebw. 109 Scotch pine sapwood	35.26 31.61 32.07 25.06 27.07 32.16	30.5	20.0
Poria placenta FPRL 280 Scotch pine sapwood	24.26 23.05 20.81 20.99 25.65 26.67	23.6	20.0

Recalculated results for product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* indicated that the *b.r.v (biological reference value*) were 12.1 kg/m^3 against *C. puteana*, 12.15 kg/m^3 against *G. trabeum* and 12.15 kg/m3 against *P. placenta*

2.5.3.2 Wood boring beetles

In this study conducted according to a test standard PN-EN 46-1:2009, *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* was tested for efficacy against wood boring beetles (recently hatched larvae of *Hylotrupes bajulus*).

The blocs used in the test were artificially aged according to PN-EN 73:1993.

Table 2.4 Summary results for *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* (6 replicates)

Solution retention [g/m^2]	Number of larvae			Number of larvae not recovered [n]
	Dead		Alive [n]	
	Not gnawed [n]	Gnawed [n]		
498.4	6	4	0	0
500.0	9	1	0	0
498.4	4	6	0	0
500.0	7	3	0	0
499.2	6	4	0	0
499.2	8	2	0	0

The test results indicated that, following treatment at an application rate of 500 g/m^2 of ready to use product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* all larvae are dead.

As 90 – 100 % of the larvae exposed to the untreated control test specimens and of those exposed to control test specimens treated with the solvent survived, therefore the test is valid.

2.5.4 Discussion

2.5.4.1 Wood destroying basidiomycetes

The study conducted according to PN-ENV 839 was carried out at rate 200 g/m^2 and 250 g/m^2 of ready to use product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP*.

The study demonstrated that product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* is efficient in rate 200 g/m^2.

Dipping application method used in the test is the superficial treatment. Painting/brushing is also a superficial method and in the Polish Competent Authority view, the results support requested application by brushing.

According to European standard PN-EN 599-1, the critical value (*c.v.)* is the highest *b.r.v* from all of the biological tests carried out on the product. Therefore the *c.v.* derived in the test study conducted according to PN-EN 113 on product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* is 12.15 kg/m^3.

Test standard PN-EN 599-1 states (section 5.2.15) that for superficial treatments, the *b.r.v* in grams per square metre shall be deemed to be equivalent to twice the *b.r.v* established in kilograms per cubic metre. On this basis the c.v. of 12.15 kg product m^3 is equivalent to an application rate of 24.3 g product/m^2 (0.73 g boric acid/m^2 and 0.24 g disodium tetraborate/m^2).

The application rate against wood destroying basidiomycetes for the product is 200 g/m^2 (6 g boric acid/m^2 and 2 g disodium tetraborate/m^2).

Therefore, the data supports the proposed by Applicant application rate for superficial treatment against wood destroying basidiomycetes with *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP*.

For the above reasons Polish Competent Authority considers the data to be acceptable in support of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP*.

2.5.4.2 Wood boring beetles

The PN-EN 46-1 study demonstrated the efficacy of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* as a preventive wood preservative against wood boring beetles at a application rate of 500 g product/m^2 (15 g boric acid/m^2 and 5 g disodium tetraborate/m^2).

The Applicant has indicated that the application rate of the product against wood boring beetles is 500 g product m^2 (15 g boric acid/m^2 and 5 g disodium tetraborate/m^2). Therefore the results support proposed application rate of the product.

The Applicant has declared that the product is intended for use in 1 & 2 wood use classes. On the basis on *TNsG* on Product Authorisation, Appendices to Chapter 7, Product Type 8, Section 2.2.1, the submitted data meet the required criteria for use classes 1 & 2.

For the above reasons Polish Competent Authority considers the data to be acceptable, in support of *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP*.

2.5.5 Conclusion

Sufficient data confirming efficacy in declared field of use have been generated on the product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP*.

2.6 Exposure assessment

2.6.1 Description of the intended use

Wood Protector przeciwogniowy impregnat do drewna FIRESTOP is a ready-to-use wood preservative for preventive use against wood destroying basidiomycetes and wood boring beetle. Biocidal product is intended to use in use class 1 (UC1 – wood or wood-based product under cover and fully protected from the weather, not exposed to wetting) and in use class 2 (UC2 – wood or wood-based product under cover and fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting).

The biocidal product is intended for professional and non-professional users, recommended method of application is painting and/or brushing.

The *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* contains 3% w/w of boric acid and 1% w/w disodium tetraborate. Both substances are relevant for the risk assessment of the biocidal product. The toxic effects of them are similar and in both cases due to the content of boron. Therefore, in the exposure calculations the active substances will be

expressed as B (boron) equivalents; the conversion factors for boric acid and disodium tetraborate into equivalent doses of boron are 0.175 and 0.215, respectively.

2.6.2 Assessment of exposure to humans and the environment

The biocidal product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* contain two active substance: boric acid and disodium tetraborate and one substance of concern – quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides (CAS 85409-22-9), trade name *Barquat MS 100*, classified and labelled under CLP regulation 1272/2008. The *Barquat MS 100* concentration in the product is very low (0.13%) and does not affect on overall classification of product. Please see Document IIIB6.5 for details.
New exposure studies have not been submitted and the risk assessment was performed based on the information presented in Competent Authority Reports for boric acid and disodium tetraborate [2].

2.7 Risk assessment for human health

The biocidal product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* has been tested from toxicological point of view. However, information about toxicokinetics, critical endpoints and assessment factors presented in this section are taken from the final ARs on boric acid and disodium tetraborate to which the letter of access form the EBA A.I.S.B.L. has been submitted.

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

Critical endpoints and assessment factors

Overall NOAEL

The toxicological data base reveals that the major targets for toxicity of borates are the testes and the blood. In the repeated dose studies with mouse, rat and dog, consistently effects on the testes and on blood parameters were found. In a 90 days study in the mouse the Animals appeared to be more sensitive to the effects on the haematopoietic system than on the testes. In the rat effects on both the testes and on the blood were observed at dose levels of

[2] Competent Authority Reports available at *https://circabc.europa.eu*

334 mg boric acid/kg b.w./day. The NOAEL in this study was 100 mg/kg b.w./day (17.5 mg B/kg b.w./day). Similar results were obtained from studies with disodium tetraborate decahydrate at equimolar doses of boron. Based on the NOAEL for embryotoxic/teratogenic effects of boric acid of 55 mg/kg b.w./day (9.6 mg B/kg b.w./day) the overall NOAEL is 9.6 mg B/kg b.w./day.

Total assessment factor

The available information on kinetics and dynamics does not allow refinement of the standard assessment factors (10 for interspecies variation and 10 for intraspecies variation). There are indications that the sensitivity for the effects on the testes does not differ markedly between subchronic and chronic exposure. Therefore the application of an additional assessment factor for extrapolation from subchronic to chronic exposure is not required.

AOEL (acceptable operator exposure level)

Using the standard assessment factor of 100 (10 for interspecies- and 10 for intraspecies variation) an oral AOEL of 0.096 mg B/kg b.w./day can be derived based on the NOAEL for embryotoxic/teratogenic effects of boric acid of 9.6 mg B/kg b.w./day. Based on the NOAEL of 17.5 mg B/kg b.w./day in a 2-year study in the rat and an assessment factor of 300 due to serious effects and based on the NOAEL of 21.8 mg B/kg b.w./day in a teratogenicity study in the rabbit and an assessment factor of 300 due to serious effects AOEL values can be derived of 0.06 and 0.07 mg B/kg b.w./day, respectively. For the risk assessment, a rounded (systemic) AOEL value of 0.1 mg B/kg b.w./day was used for boric acid, even though values of 0.06 and 0.07 mg B/kg b.w./day could be derived from the critical effects.

MOE (margin of exposure)

For the risk assessment of borates the systemic NOAEL of 9.6 mg/kg b.w./day will be used. A MOE of 100 would be considered acceptable, on the basis of the standard assessment factors of 100 (10 x 10) for interspecies and intraspecies variability.

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product contains one substance of concern – quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides (CAS 85409-22-9), trade name *Barquat MS 100*, classified and labeled under CLP regulation 1272/2008. The *Barquat MS 100* concentration in the product is very low (0.13%) and does not affect on overall classification.

2.7.1.3 Toxicology of the biocidal product

Toxicokinetics

Absorption of borates via the oral route is nearly 100%. For the respiratory route also 100% absorption is assumed. Dermal absorption through intact skin is very low. For risk assessment of borates a dermal absorption of 0.5% is used. In the blood boric acid is the main species present. Boric acid is not further metabolised. Boric acid is distributed rapidly and evenly through the body, with concentrations in bone 2-3 higher than in other tissues. Boron is excreted relatively rapidly with elimination half-lives of 1h in the mouse, 3h in the rat and 21h in humans, and has low potential for accumulation. Boric acid is mainly excreted in the urine.

Acute toxicity

The biocidal product is of low acute toxicity: LD_{50} oral rat > 2000 mg/kg; LD_{50} dermal rat >2000 mg/kg.

Irritation and Corrosivity

The biocidal product is not a skin irritant or an eye irritant.

Sensitization

The biocidal product is non-sensitizer, on the basis of a guinea pig maximization test.

2.7.2 Exposure

The exposure to borates is calculated by using the selected models and default values for wood preservatives from the *User Guidance TNsG*[3] as a guideline. In the calculations the process information given by the notifier is used as a base for the calculation.

The exposure for users is related to painting and/or brushing method of application. It is also assumed that non-professional user use the biocidal product only occasionally.
There are three main paths of exposure – oral, dermal, inhalation which should be taken into account in human exposure assessment.

[3] *Technical Notes for Guidance (TNsG). Human Exposure to Biocidal Products – Guidance on Exposure Estimation. Contract B4-3040/2000/291079/MAR/E2. DG Environment June 2002.User Guidance, Version 1 belonging to Report Human Exposure to Biocidal Products* (TNsG June 2002). Available from http://ecb.jrc.it

The treated wood is not placed on the market until it is dry. Use of biocidal product on wood, which is likely to come into prolonged direct contact with foodstuffs or feedstuffs is not expected.

Indirect exposure via the environment is considered not relevant based upon the rapid environmental degradation of biocidal product ingredients.

2.7.2.1 Exposure of professional and non-professional users

Assumptions used in the estimations of exposure:

- the total content of active substances is 4% w/w,
- the total content of active substances in product ready to use expressed as B equivalents is 3% boric acid × 0.175 + 1% disodium tetraborate × 0.215 = 0.0074 B equivalents
- the application rate for worst case scenario as 1 kg product/m^2 (40 g a.s./m^2)
- default factor 0.1 for the use of PPE

Based on List of Endpoints for boric acid for calculation it was assumed:

- rate and extent of dermal absorption: 0.5%
- rate and extent of oral absorption: 100%
- rate and extent of inhalation absorption: 100%.

<u>Non-professional exposure: painting/brushing</u>

The exposure is calculated by using models and default values for wood preservatives from the *User Guidance TNsG* as a guideline. For calculating the exposure during painting/brushing, the model 'Consumer Product Painting: Model 3' (75th percentile; *TNsG*) is used which described the potential dermal exposure as well as the inhalation exposure. probability of potential dermal exposure is 16.9 mg product/min

- probability of exposure by inhalation – 4.15 mg of product ready to use/m^3
- inhalation rate – 0.021 m^3/min
- use: 1 days/year (see: *User Guidance TNsG*, 1-2 days/year)
- 155 min/day
- no PPE

Acute systemic exposure:

dermal exposure: 19.38 mg B/day × 0.005 = 0.097 mg B/day = 0.0016 mg B/kg b.w./day

inhalation exposure: 0.1 mg B/day × 1 = 0.1 mg B/day = 0.0017 mg B/kg b.w./day

Professional exposure: painting/brushing

The exposure is calculated by using models and default values for wood preservatives from the *User Guidance TNsG* as a guideline. There is no exposure models for professional painters, therefore, the exposure is assessed based on the model 'Consumer Product Painting: Model 3' (75th percentile; *TNsG*).

- potential dermal exposure is 16.9 mg product/min
- potential exposure by inhalation – 4.15 mg of product ready to use/m^3
- inhalation rate – 0.021 m^3/min
- use 4 hours/day (see: *User Guidance TNsG* the use of preservative by professionals is less than half the time spent at the job)
- during the application and post-application phase gloves, coverall and respiratory protective equipment are used. In 'Consumer Product Painting: Model 3' the exposure with PPE is not stated, only the exposure inside gloves and inside shoes, which is approximately 5.8 % of the potential dermal exposure. The exposure inside gloves and inside shoes certainly isn't the total dermal exposure with PPE. Therefore, the default factor of 0.1, which is common practice in the UE and stated in the *TNsG*.

Chronic systemic exposure:

- without PPE

dermal exposure: 30.1 mg B/day × 0.005 = 0.15 mg B/day = 0.0025 mg B/kg b.w./day

inhalation exposure: 0.15 mg B/day × 1 = 0.15 mg B/day = 0.0025 mg B/kg b.w./day

- with PPE

dermal exposure: 0.00025 mg B/kg b.w./day

inhalation exposure: 0.00025 mg B/kg b.w./day

2.7.2.2 Indirect exposure as a result of use of the active substance in biocidal product

Indirect exposure to borates as a result of use can occur during the use of timber treated with wood preservatives. Treated timber could be used for playground structures outdoors but under cover where high environmental humidity can lead to occasional wetting. Children playing at these constructions could be exposed to borates by contacting the wood. In the *User Guidance TNsG* a 'reference scenario' for children playing on playground structures outdoors is described. This scenario will be starting point of the exposure assessment.

The 'indirect exposure as a result of use' is mainly based on assumptions and not on measurements nor on default values derived from measurements. Therefore the result of the exposure assessment must be seen as an indication of the order of magnitude.

2.7.2.3 Exposure of a child playing on playground structure outdoors

Scenario: Child playing on playground structure outdoors but under cover where high environmental humidity can lead to occasional wetting. The structures are made of wood, which has been treated with wood preservative and there is prolonged and repeated contact of wood with hands, which causes dermal exposure. Oral exposure may occur via hand-to-mouth transfer. It is assumed that 10% of the dermal exposure to borates is ingested orally due to hand-to-mouth transfer.

Child, 2-5 years of age, 16.7 kg.

Exposure hands

Surface loading of boron in treated wood: 0.01 mg/cm^2 wood × 0.0074 B equivalents = 0.000074 mg B/cm^2

Hand surface area = 200 cm^2

Assume 20% of hand (40 cm^2) contaminated at 100% of surface concentration

Total exposure on the hands = 0.000074 × 40 = 0.003 mg B/day

It is assumed that 10% of the total exposure that ends up on the skin of a child is taken in orally due to hand-mouth contact.

Dermal exposure 0.9 × 0.003 = 0.0027 mg B/day

Dermal absorption factor: 0.005

Internal chronic dermal exposure = 0.0027 [mg B/day of exposure] × 0.005 / 16.7 [kg b.w.] = 0.00000081 mg B/kg b.w./day

Oral exposure due to hand-mouth contact: 0.1 × 0.003 = 0.0003 mg B/day

Oral absorption factor: 1

Internal chronic oral exposure = 0.0003 [mg B/day of exposure] / 16.7 [kg b.w.] = 0.000018 mg B/kg b.w./day

2.7.3 Risk Characterisation

The risk characterization was performed in accordance with the recommendations of the technical guidelines *TNsG* (Annex I Inclusion Revision of Charter 4.1: Quantitative Human Health Risk Characterisation), based on the determined values of MOE and AEL.

2.7.3.1 Risk for non-professional users

Table 2.5 Risk assessment of biocidal product – without PPE

Exposure	Estimated exposure [mg B/kg b.w./day]	AOEL systemic [mg B/kg b.w./day]	Risk index
Painting/brushing	0.0033	0.1	0.033

Table 2.6 Risk assessment of biocidal product – without PPE

Exposure	Estimated exposure [mg B/kg b.w./day]	NOAEL systemic [mg B/kg b.w./day]	MOE
Painting/brushing	0.0033	9.6	2 909

Based on the AOEL approach and MOE approach it can be concluded that adverse health effects for the unprotected professional users due to the combined dermal and respiratory exposure to *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* can be excluded (risk index < 1 and MOE > 100).

2.7.3.2 Risk for professional users

Table 2.7 Risk assessment of biocidal product

Exposure	Estimated exposure [mg B/kg b.w./day]		AOEL systemic [mg B/kg b.w./day]	Risk index	
	without PPE	with PPE		without PPE	with PPE
Painting/ brushing	0.005	0.0005	0.1	0.05	0.005

Table 2.8 Risk assessment of biocidal product

Exposure	Estimated exposure [mg B/kg b.w./day]		NOAEL systemic [mg B/kg b.w./day]	MOE	
	without PPE	with PPE		without PPE	with PPE
Painting/ brushing	0.005	0.0005	9.6	1 920	19 200

Based on the AOEL approach and MOE approach it can be concluded that adverse health effects for the unprotected professional users due to the combined dermal and respiratory exposure to *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* can be excluded (risk index < 1 and MOE > 100).

2.7.3.3 Indirect exposure as a result of use of the active substance in biocidal product

Table 2.9 Risk assessment of biocidal product – without PPE

Exposure	Estimated exposure [mg B/kg b.w./day]	AOEL systemic [mg B/kg b.w./day]	Risk index
Exposure of a child playing on playground structure outdoors	0.0000188	0.1	0.000188

Table 2.10 Risk assessment of biocidal product – without PPE

Exposure	Estimated exposure [mg B/kg b.w./day]	AOEL systemic [mg B/kg b.w./day]	Risk index
Exposure of a child playing on playground structure outdoors	0.0000188	9.6	510 367

For child playing on a playground structure outdoors (but under cover where high environmental humidity can lead to occasional wetting) a health risk as a consequence of exposure to borates can be excluded.

2.8 Risk assessment for the environment

Wood Protector przeciwogniowy impregnat do drewna FIRESTOP is a water based ready to use formulation for use as a wood preservative against wood destroying basidiomycetes and wood boring beetle.

Biocidal product is intended to use in use class 1 (UC1 – timber under cover and fully protected from the weather, not exposed to wetting) and in use class 2 (UC2 – timber under cover and fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting).

2.8.1 Fate and distribution in the environment

The biocidal product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* contains two active substances: boric acid (3%) and disodium tetraborate (1%) and one substance of concern – quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides (CAS 85409-22-9), trade name *Barquat MS 100*, classified and labelled under CLP regulation 1272/2008. The *Barquat MS 100* concentration in the product is very low (0.13%) and does not affect on overall classification of product.

Therefore only active substances are considered as of concern for environment and the risk characterisation can be performed only for these substances. Data necessary to estimate fate and behaviour of these substances were derived from the Competent Authority Report for boric acid and disodium tetraborate.

The characteristics of active substances including lists of endpoints are available in Competent Authority Reports for boric acid and disodium tetraborate. Applicant confirmed access to those data by the Letter of Access for boric acid and disodium tetraborate.

2.8.2 Emission to environmental compartments

The product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* is intended to used in UC1 and UC2. No emission scenarios are available for these Use Classes, since the potential risk from treated wood to the outer environment is considered negligible. Therefore, there is no necessity to assess the environmental risk.

Assuming that wood is preserved/stored after treatment outdoor, emission to the environment is possible. Since there is no dedicated scenario for such application, scenario for treatment by brushing of wooden fence was adopted to calculate emission to the environment (for further explanation see Document IIB).

Emission, fate and behaviour in the environment were considered jointly for boric acid and disodium tetraborate because disodium tetraborate are converted into boric acid/borate upon dissolution in water. The same way as in Competent Authority Reports for active substances it is assumed that boric acid will be the predominant species in environmental compartments. Predicted Environmental Concentrations of active substances in environmental compartments

(PEC's) were converted to boron concentration (for further explanation see Document IIB). These values were compared to Predicted No Effect Concentrations (PNEC's) derived from Competent Authority Reports for boric acid and disodium tetraborate. PNEC's values for both active substances were also expressed as concentration of boron.
It has to be noted that boron is present in natural environments. Therefore the PEC's and PNEC's mentioned in this document are PEC_{add}'s and $PNEC_{add}$'s, added concentrations on top of the background concentration, due to emission of boric acid to the environment.

The analysis of the results obtained in efficacy studies shows that in superficial application the minimum amount of the product for wood protection against wood destroying basidiomycetes is 200 g/m^2 of wood (two or more coats) and 500 g/m^2 against wood destroying basidiomycetes and wood boring beetles (four or more coats). Therefore amount 500 g/m^2 was used to calculate the emission.
According to declaration of Applicant biocidal product *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* is a fire retardant. This is not evaluated by Polish Competent Authority because it is not biocidal activity. However for sake of completeness the highest declared by Applicant application rate (1 kg of product per m^2 of wood) was also considered in assessment.

2.8.3 Environmental risk assessment

2.8.3.1 Aquatic compartment

2.8.3.1.1 Surface water and sediment

According to the *ESD*[4], no emission to surface water is expected during the outdoor treatment process. Emission during indoor use is negligible. Therefore risk estimation for water is not necessary.

2.8.3.1.2 Sewage treatment plant

There is no emission to STP during outdoor application and storage. Emission during indoor use is negligible. Therefore risk characterisation is not necessary.

[4] *OECD serried on Emission Scenario Documents, number 2, Emission Scenario Document for Wood Preservatives,* OECD 2003

2.8.3.2 Atmosphere

Due to the low volatility of the inorganic borates, emission to air is very low. Therefore estimation of risk for atmosphere is considered to be not necessary.

2.8.3.3 Terrestrial compartment

According to the *ESDs* it is assumed that during application of wood preservative on wood outdoor and then leaching from treated wood soil is only compartment exposed.

A $PNEC_{add,soil}$ of 0.4 mg $B/kg_{dwt\ soil}$, which is equivalent to 0.35 mg $B/kg_{wwt\ soil}$ was derived from Competent Authority Reports for boric acid and disodium tetraborate. This value is compared with values of $PEC_{add,soil}$ to estimate risk for soil.

Table 2.11 $PEC_{add,soil}/PNEC_{add,soil}$ ratio for terrestrial compartment – leachable area 4m^2

	4 m^2 of wood per 1m^2 of soil			
	$PEC_{add,soil}$ [mg B/kg wwt]		**PEC/PNEC**	
	biocidal	**fire ret.**	**biocidal**	**fire ret.**
Outdoor application (amateur)	0.87	1.74	2.49	4.97
Outdoor application (professional)	0.52	1.04	1.49	2.97
Outdoor storage	17.4	34.8	49.7	99.4
Storage + application (amateur)	18.4	36.8	52.6	105.2
Storage + application (professional)	17.9	35.8	51.1	102.3

Table 2.12 $PEC_{add,soil}/PNEC_{add,soil}$ ratio for terrestrial compartment - leachable area 11m^2

	11 m^2 of wood per 1m^2 of soil			
	$PEC_{add,soil}$ [mg B/kg wwt]		**PEC/PNEC**	
	biocidal	**fire ret.**	**biocidal**	**fire ret.**
Outdoor application (amateur)	2.39	4.78	6.83	13.66
Outdoor application (professional)	1.43	2.46	4.09	7.03
Outdoor storage	47.85	95.70	136.71	273.43

All PEC/PNEC ratios are >1, indicating potential risk for soil during outdoor application and storage of preserved wood.

2.8.4 Risk characterisation for groundwater used as drinking water

Since the *TGD*[5]does not mention a method to calculate a $PNEC_{add, grw}$, a risk assessment for groundwater could not be performed on the basis of a $PEC_{add}/PNEC_{add}$ comparison. The calculated $PEC_{add,grw}$ are evaluated according to the criteria for water that will be used for production of drinking water. The limit value for boron is 1 mg B/L. Therefore permissible concentration is exceeded during storage of protected wood outdoor, exposed to rain (see Document II B).

2.8.5 Non compartment specific effects relevant to the food chain (secondary poisoning)

Boron is an essential micronutrient for all plants and is applied as an agricultural fertiliser. Borates are therefore part of an everyday diet of fresh fruit and vegetables. While boron may accumulate in plants and some animals relative to their immediate environment, there is evidence from field studies that boron is not bioconcentrated or bioaccumulated along the food chain (for further explanation please see Competent Authority Reports for boric acid and disodium tetraborate).

2.8.6 PBT assessment

PBT assessment has to be done according to the *TGD* especially for substances which can be shown both to persist for long periods and bioaccumulate in biota, and can give rise to toxic effects after a greater time and greater distances than chemicals without these properties.
Substances which fulfil the PBT or vPvB criteria will not be included in Annex I unless releases to the environment can be effectively prevented.
Being an inorganic compound, boron does not biodegrade in marine or freshwater and sediments, and should therefore be considered as Very Persistent (vP). Boron is not bioconcentrated, based on the available data the BCF is < 2000 L/kg wwt.

[5] *Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances. Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market*. Part II. Published.

The chronic NOEC of boron for marine or freshwater organisms is > 0.01 mg B/L, moreover boron is not considered to have endocrine disrupting effects. However, based on CMR data, boron is classified with Toxic for reproduction category 2 and assigned risk phrases R60 and R61 (see Competent Authority Report for boric acid or disodium tetraborate). Therefore, boron should be considered as fulfilling the criteria for Persistence and Toxicity, but not for Bioaccumulation.

Conclusion: Since boron does not meet criteria *B*, the substance is not considered a PBT candidate.

2.9 Measures to protect man, animals and the environment

Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying the following appropriate and available risk mitigation measures:

1. Authorisation is granted for Use Class 1 (wood or wood-based product under cover and fully protected from the weather, not exposed to wetting) and Use Class 2 (wood or wood-based product under cover and fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting).

2. Treated timber must not be permanently exposed to weather or used in external situations where it is in contact with the ground or in permanent contact with fresh or salt water.

3. The preserved wood must be used only indoor or outdoor under cover and fully protected from the weather.

4. Preserved wood must be protected from leaching until the roofing.

5. Always read the label before use and follow the instructions provided.

6. Avoid contact with skin and eyes.

7. Contaminated gloves should be cleaned or disposed. Do not allow that water used for cleaning gloves get into the soil, surface water or sanitary sewer system.

8. Suitable personal protective equipment (coveralls, gloves, foot protection, eye protection glasses and respiratory protective equipment) are recommended when applying the product and when handling freshly treated timber. Avoid excessive contamination of protective equipment.

9. In case of accident (e.g. if swallowed, contact with eyes) or if you feel unwell seek medical advice immediately (show packaging and the label).

10. Wash hands and exposed skin before meals, drinking, smoking and after use.

11. Do not mix with other products.

12. The working area should be ventilated adequately by natural or mechanical means.

13. Freshly treated wood should be stored in areas with good ventilation.

14. The treated wood is not placed on the market until it is dry.

15. Eating, drinking and smoking should be prohibited in areas where this product is handled, stored and processed.

16. Do not use for wood in direct contact with food, feeding stuffs and drinking water.

17. Biocidal product should not be used where food, feeding stuffs or drinking water could be contaminated.

18. Do not contaminate ground, waterbodies or watercourses with biocidal product or used container.

19. The product cannot be used close to water.

20. Do not contaminate plant life. Cover ground and all water storage tanks before application

21. Avoid release to the environment.

22. Avoid contamination of soil, surface water or sanitary sewer system from product or packaging the product.

23. In case of accidental release of product into the environment, it should be collected with non-combustible, absorbent material e.g. sand, earth, vermiculite and place in labeled container for disposal and deliver to authorised company which are empowered to utilization of hazardous wastes and their disposal. During collect avoid direct contact with the skin.

24. Do not empty into drains.

25. If the product contaminates lakes, rivers, or sewers, inform the appropriate authorities in accordance with local regulations.

26. Product contains substances potentially dangerous to bat..

27. Product should be stored in original, labelled and closed containers in cool, dry and well-ventilated area.

28. Keep in a safe place.

29. Keep out of the reach of children.

30. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Moreover it should be tightly closed and stored in vertical position precluding efflux.

31. This material and its container must be disposed of in a safe way.

32. Packaging of the product, any contaminated materials (i.e. water used for cleaning of contaminated surface, protective foil, cleaning solvent), unused product, the remains of the product after use (closed in a labeled container) and the out-of-service treated wood must be treated as hazardous waste and delivered to authorised company which are empowered to utilization of hazardous wastes and their disposal.

33. Package cannot be reused and be used for any other purpose.

3 Proposal for decision

1. Product Formulation

Active substance content	% w/w	Manufacturer of active substance
Boric acid	3	please refer to PAR section: *Manufacturer of active substance used in the biocidal product*
Disodium tetraborate	1	

2. Formulation type	liquid
3. Product type	PT8
4. User	non-professional and professional
5. Packaging	please refer to PAR section 2.2.3
6. Application Method	painting/brushing
7. Application Rate	▪ 200 g product/m^2 in 2 or more coats against wood destroying basidiomycetes (6 g boric acid/m^2 and 2 g disodium tetraborate/m^2); ▪ 500 g product/m^2 in 4 or more coats against wood boring beetles (15 g boric acid/m^2 and 5 g disodium tetraborate/m^2)
8. Organism controlled	▪ Wood destroying basidiomycetes: - *Coniophora puteana*, - *Gloeophyllum trabeum*, - *Poria placenta* ▪ Wood boring beetle: - *Hylotrupes bajulus*, larvae
9. Shelf life	up to 2 years
10. Expiry data of the authorisation	10 years after authorisation granting
11. Any other specific conditions:	please refer to PAR section 2.9.

Annex 1: List of studies reviewed

List of <u>new data</u> submitted in support of the evaluation of the biocidal product

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
IIIB	3.1.1 3.1.2 3.1.3 3.5 3.6 3.7 3.8	Al Amin Idris	2011	Wood Protector przeciwogniowy impregnat do drewna FIRESTOP. Determination of physicochemical properties. Institute of Industrial Organic Chemistry, Warsaw Report No. EMC Nr 373800019, Study code No. BF-24/11,	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐
IIIB	4.1	Drożdżewska Katarzyna	2011	Badania analityczne "Przeciwogniowego Impregnatu do drewna Wood Protector FIRESTOP" Instytut Przemysłu Organicznego, Warszawa Report No EMC Nr 373800023 Study code No BA-13/11	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐
IIIB	5.10-01	Abram Alicja	2011	Wood Protector przeciwogniowy impregnat do drewna Firestop koncentrat Instytut Techniki Budowlanej, Warszawa, 2011 Test Report No LM 02-2265/10/Z00NM	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB	5.10-02	Abram Alicja	2011	Wood Protector przeciwogniowy impregnat do drewna Firestop koncentrat Instytut Techniki Budowlanej, Warszawa, 2011 Test Report No LM 01-2265/10/Z00NM	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐
III-B	5.10-03	Fennert Eva-Maria, Doblinski M.	2010	Determination of the preventive action against recently hatched larvae of *Hylotrupes bajulus* (L.) according to EN 46-1 (2009) after evaporative ageing procedure according to EN 73 (1988). Wood Protector Firestop Koncentrat MPA Eberswalde, Test report No. 32/10/9443/02A	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐
IIIB	6.1.1	Kupny Joanna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Acute oral toxicity study – fixed dose method on rats according to the OECD Guideline No 420/EU Method B.1.BIS. Institute of Industrial Organic Chemistry Branch Pszczyna, Study code: PO-8/11,	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB	6.1.2	Kupny Joanna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Acute dermal toxicity study on rats according to the OECD Guideline No 402/EU Method B.3. Institute of Industrial Organic Chemistry Branch Pszczyna Study code: DER-8/11	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐
IIIB	6.2.1-1	Gruszka Katarzyna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. *In vitro* skin corrosion: Transcutaneous electrical resistance test (TER) according to the OECD Guideline No 430/EU Method B.40. Institute of Industrial Organic Chemistry Branch Pszczyna Study code:OES-4/11	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐
IIIB	6.2.1-2	Krupny Joanna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Acute skin irritation/corrosion study on rabbits according to the OECD Guideline No 404/EU Method B.4. Institute of Industrial Organic Chemistry Branch Pszczyna Study code: DDR-10/11,	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB	6.2.2-1	Gruszka Katarzyna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants according to the OECD Guideline No 438/EU Method B.48. Institute of Industrial Organic Chemistry Branch Pszczyna Study code: ICE-1/11	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐
IIIB	6.2.2-2	Kupny Joanna, Fochtman Przemysław	2011	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Acute eye irritation/corrosion study on rabbits according to the OECD Guideline No 405/EU Method B.5. Institute of Industrial Organic Chemistry Branch Pszczyna Study code:ODR-12/11	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐
IIIB	6.3	Kupny Joanna, Fochtman Przemysław	2012	WOOD PROTECTOR przeciwogniowy impregnat do drewna FIRESTOP Koncentrat. Skin sensitization study according to the OECD Guideline No 406/EU Method B.6. Institute of Industrial Organic Chemistry Branch Pszczyna Study code:Al-7/11	Dekspol P.P.H. Iwona Oleszak	☐	☒	☒	☐

Annex 2: Analytical methods residues – active substances

< Boric acid >
< Disodium tetraborate >

No new data for the active substances residues was submitted. For datailed information please see the Competent Authority Reports for active substances boric acid and disodium tetraborate.

Annex 3: Toxicology and metabolism –active substances

< Boric acid >
< Disodium tetraborate >

No new data for the active substances was submitted. For datailed information please see the Competent Authority Reports for active substances boric acid and disodium tetraborate.

Annex 4: Toxicology – biocidal product

< *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* >

General information

Formulation Type:	liquid
Active substance(s) (incl. content)	3% boric acid, 1% disodium tetraborate
Category	PT 8 – wood preservatives

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD_{50} oral (OECD 420)	> 2 000 mg/kg b.w.
Rat LD_{50} dermal (OECD 402)	> 2 000 mg/kg b.w.
Rat LC_{50} inhalation (OECD 403)	-
Skin irritation (OECD 404)	Non irritat
Eye irritation (OECD 405)	Non irritat
Skin sensitisation (OECD 429; LLNA)	Non sensitiser

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	Not required
Toxicological data on active substance(s) (not tested with the preparation)	For datailed information please see the Competent Authority Reports for active substances boric acid and disodium tetraborate.
Toxicological data on non-active substance(s) (i.e. substances of concern)	The biocidal product contains one substance of concern – quaternary ammonium compounds, benzyl-C12-14-alkyldimethyl, chlorides (CAS 85409-22-9), trade name *Barquat MS 100*, classified and labeled under CLP regulation 1272/2008. The *Barquat MS 100* concentration in the product is very low (0.13%) and does not affect on overall classification of product. Please see Doc.IIIB6.5 for details.
Further toxicological information	Not required

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	None
Regulation EC 1272/2008	None

Annex 5: Safety for professional operators

< *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* >

See point 2.7.3.2 above

Annex 6: Safety for non-professional operators and the general public

< *Wood Protector przeciwogniowy impregnat do drewna FIRESTOP* >

See point 2.7.3.1 above

Annex 7: Residue behaviour

< Boric acid >
< Disodium tetraborate >

No new data for the active substances was submitted. For datailed information please see the Competent Authority Reports for active substances boric acid and disodium tetraborate.